FILED UNDER SEAL - CONTAINS INFORMATION MARKED AS CONFIDENTIAL UNDER THE DISCOVERY CONFIDENTIALITY ORDER.

April 11, 2023

VIA ECF

Hon. Cathy Waldor, U.S.M.J.
U.S. District Court for the District of New Jersey
50 Walnut Street, Room 4040
Newark, NJ 07102

Re: ***Johnson & Johnson Health Care Systems, Inc. v. Save On SP, LLC***
No. 2:22-cv-02632 (ES) (CLW)

Dear Judge Waldor:

Plaintiff Johnson & Johnson Health Care Systems Inc. ("JJHCS") seeks the Court's intervention at the April 13 conference to compel Defendant Save On SP, LLC ("SaveOnSP") to provide substantive and complete responses to two interrogatories served on February 7, 2023. The SaveOnSP responses and objections at issue are attached as Exhibit 1.

The parties have met and conferred in good faith to resolve their disputes concerning these interrogatories, but were unable to do so. We therefore submit this letter in accordance with Local Rule 37.1 and the Court's Civil Case Management Order.

I. JJHCS INTERROGATORY NO. 15

"Describe whether and under what circumstances You have advised any Payors to eliminate or alter coverage for certain pharmaceuticals and to arrange for Plan Members to obtain those pharmaceuticals from any source other than Accredo, including (without limitation) independent nonprofit organizations, such as the Johnson & Johnson Patient Assistance Foundation, Inc."

JJHCS's Position

This interrogatory seeks information about how SaveOnSP's scheme operates. The "Accredo" referenced in the interrogatory is the specialty pharmacy with which SaveOnSP typically works. Complaint ¶ 28. SaveOnSP has refused to answer this interrogatory altogether.

As the Court knows, JJHCS alleges that SaveOnSP unlawfully enriches itself and its health insurance partners by diverting critical patient assistance provided by JJHCS that is meant to help patients access the medication they need to treat cancer and other serious illnesses. *See, e.g.*, Compl. ¶¶ 1-5, 8-17, 50-88. SaveOnSP does this by committing various deceptive acts, including outright misrepresentations to patients and drug manufacturers alike. *Id.* ¶¶ 11-16, 60-67, 73-88.

Newly produced SaveOnSP documents indicate that the SaveOnSP Program may involve misappropriating not just copay assistance funds made available by manufacturers, but also additional manufacturer-provided patient assistance resources, like those made available through the Johnson & Johnson Patient Assistance Foundation. *See generally* About Our Programs, *Johnson & Johnson Patient Assistance Foundation, Inc.*, https://www.jjpaf.org/about/ (last visited March 29, 2023) ("JJPAF gives eligible patients free prescription medicines donated by Johnson & Johnson companies.").

For example, a recently produced document shows [redacted] SOSP_0019015 at 015-016, attached as Exhibit 2. [redacted]

Schemes like this are under increasing scrutiny. Entities, apparently including SaveOnSP, can persuade employer health plans "to exclude some or all specialty drugs from the employee benefit plan formulary," which allows them to disguise employees as supposedly "uninsured" and therefore eligible for free prescription medicine from a manufacturer foundation. *See* Dawn Holcombe, "Specialty Carve-Outs: What Are the Implications for Patients and Practices?" *Oncology Practice Mgmt.* (Dec. 2022), attached as Exhibit 3. The end result is that (1) the drug manufacturer has been deceived into providing free drug to a patient who is not actually uninsured out of resources made available for the uninsured; (2) the patient has been deceived or confused into believing that they have lost their insurance coverage, and often also suffers through delays and administrative hurdles before finally receiving their therapy; and (3) the middleman (here, SaveOnSP) collects a large fee based on what the drug might have cost if the insurer had actually paid for it. *See id.*; *see also* Adam J. Fein, "The Shady Business of Specialty Carve-Outs, a.k.a., Alternative Funding Programs," *Drug Channels* (Aug. 2, 2022), attached as Exhibit 4 ("Naturally, the vendor skims a healthy share of the charity's money.").

If SaveOnSP is doing this—[redacted]—then it is discoverable as potentially relevant to (among other things) JJHCS's deceptive trade practices claim under the New York General Business Law. *See, e.g.*, *Gregory v. Gregory*, 2016 U.S. Dist. LEXIS 144554, at *9 (D.N.J. Oct. 18, 2016) (Waldor, J.) ("Relevance encompass[es] any matter that bears on, ***or that reasonably could lead to other matter that could bear on***, any issue that is ***or may be*** in the case." (emphasis supplied and quotation marks omitted)). If SaveOnSP is not engaging in this misconduct, it need only say so and will have satisfied the interrogatory. But SaveOnSP's stonewalling suggests otherwise.

SaveOnSP claims these issues are irrelevant to JJHCS's claims as set forth in its Complaint. It is true that JJHCS's Complaint focused on the copay assistance aspect of

SaveOnSP's scheme of which JJHCS had become aware. But JJHCS can hardly have set forth in its pleading originating this action every step in the SaveOnSP scheme to misappropriate the resources it makes available for its patients. JJHCS did not know every detail of the SaveOnSP scheme when it filed that pleading in May 2022. Nonetheless, JJHCS pled broadly that SaveOnSP was engaged in a "scheme to pilfer tens of millions of dollars from the financial support programs" made available "for *patients*—not for SaveOnSP or the health plans with which it partners," and stated that "payers and PBMs have devised a set of evolving schemes designed to capture the benefit of patient assistance funds." *See, e.g.*, Compl. ¶¶ 1, 50.

SaveOnSP attempts to deflect from these allegations by arguing that this interrogatory is inappropriate because it seeks information related to non-Janssen drugs. This is a red herring—to be clear, consistent with the Court's March 17 ruling, JJHCS is not currently seeking information regarding non-Janssen drugs through this interrogatory. In any event, SaveOnSP can hardly argue that JJHCS should not be allowed to learn more about SaveOnSP's misappropriation of patient assistance resources, especially where the misappropriation is part of an integrated scheme. All that is being sought here is information about SaveOnSP's ongoing conduct. The consequences of that information, including what issues should be deemed part of this case for trial, or are relevant only for other reasons such as under Federal Rule of Evidence 404(b), are for another day, and should be addressed on a full record, which this interrogatory will help develop.

Separately, SaveOnSP has generally refused to provide information in response to interrogatories that post-dates July 1, 2022, without providing any principled reason for such a cutoff. JJHCS's claims relate to ongoing conduct, as will its damages. JJHCS disagrees with SaveOnSP's suggestion that conferrals between the parties are ongoing with regard to the time period for this response. The Court should therefore direct SaveOnSP to provide a complete and accurate response to Interrogatory No. 15 through to the present date.

SaveOnSP's Position

In its Interrogatory No. 15, JJHCS continues its campaign of seeking information that has nothing to do with the claims it brought. In its Complaint, JJHCS alleges that SaveOnSP deceives patients taking Janssen drugs into enrolling in a "SaveOnSP Program," thereby inducing them to breach their contracts with CarePath and causing JJHCS to pay more in copay assistance funds. Compl. ¶¶ 110, 115. Interrogatory No. 15 concerns different allegations about an entirely different program in which health plans arrange for patients to obtain drugs from nonprofit organizations. Even were these allegations accurate (SaveOnSP disputes many of them), on its face this interrogatory asks about ***non-Janssen drugs***, something the Court has already held is irrelevant. ECF No. 89:17-25. And, to the extent the interrogatory concerns Janssen drugs, it asks about obtaining them from entities that are ***not JJHCS***. JJHCS does not explain how patients obtaining drugs from a different, independent entity could harm JJHCS at all, let alone how obtaining those drugs without the use of CarePath could cause JJHCS to spend more in CarePath funds. JJHCS cannot use discovery here to go fishing for separate claims on behalf of separate entities. *See Smith*

v. Lyons, Doughty & Veldhuius, Civ. Action No. 0-5139, 2008 WL 2885887, at *5 (D.N.J. July 23, 2008) ("Discovery should not serve as a fishing expedition during which Plaintiff searches for evidence in support of facts he has not yet pleaded.").[1] JJHCS's motion should be denied.

II. JJHCS INTERROGATORY NO. 14

"Identify any Entity or individual who has entered into any agreement, or otherwise has any obligation, to advance legal fees incurred by SaveOnSP in this action or to indemnify SaveOnSP in this action for its legal fees, for any damages, or otherwise."

JJHCS's Position

SaveOnSP has refused to answer this interrogatory too. SaveOnSP should be compelled to respond to it for three reasons.

First, as numerous courts have recognized, indemnification information can be highly relevant to assessing bias and credibility. *See, e.g., Kaplan v. S.A.C. Capital Advisors, L.P.*, 2015 U.S. Dist. LEXIS 135031, at *9 (S.D.N.Y. Sept. 10, 2015) ("[C]ourts have found that fee payment agreements that may be relevant to credibility and bias are not privileged."); *Powell v. Home Depot USA, Inc.*, 2008 U.S. Dist. LEXIS 130601, at *15-17 (S.D. Fla. June 26, 2008) (collecting cases and granting plaintiff's motion to compel the production of indemnification agreements); *Powerlift, Inc. v. Mark Indus., Inc.*, 1987 U.S. Dist. LEXIS 4823, at *4 (N.D. Ill. June 9, 1987) ("[I]ndemnification agreements, which concept includes agreements as to the payment of defense fees and costs, are relevant to credibility issues and the appropriate subject of discovery.").

Interrogatory 14 seeks information regarding indemnification for "legal fees, for any damages, or otherwise." The identity of SaveOnSP's benefactor, and its financial interests, will certainly be relevant to JJHCS's examinations of SaveOnSP's witnesses, who are undoubtedly beholden to the entity paying SaveOnSP's way in this litigation. Furthermore, insofar as SaveOnSP is being indemnified or reimbursed by a party that may ultimately give evidence in this proceeding—e.g., one or more of SaveOnSP's business partners in the pharmacy benefit management or insurance industries—any such arrangement will be relevant to examining those witnesses too. *See, e.g., Jeld-Wen, Inc. v. Nebula Glasslam Int'l*, 2008 U.S. Dist. LEXIS 18821, at *26-27 (S.D. Fla. Mar. 11, 2008) (compelling disclosure of indemnity agreement "providing potential impeachment evidence relating to possible ulterior motives for [witness's] testimony"). SaveOnSP's suggestion that these issues can be the subject of cross-examination at deposition or

[1] JJHCS's assertion that SaveOnSP has generally refused to provide information after July 1, 2022 is simply false. SaveOnSP offered to do so for some discovery requests if JJHCS—which ended its own responses as of that date—will do the same. The parties are still meeting and conferring on this point.

at trial ignores the fact that effective cross-examination is typically conducted using information developed through discovery, which SaveOnSP is refusing to produce.

Second, the federal courts have moved steadily in the direction of requiring disclosure of financial interests underlying litigation to promote transparency in the litigation process and help identify the actual decisionmakers. For example, in 2021, this Court adopted new Local Rule 7.1.1, which requires disclosure of detailed "information regarding any person or entity that is not a party and is providing funding for some or all of the attorneys' fees and expenses for the litigation on a non-recourse basis in exchange for (1) a contingent financial interest based upon the results of the litigation or (2) a non-monetary result that is not in the nature of a personal or bank loan, or insurance." While SaveOnSP contends it is not required to make any further disclosure, the same concerns about transparency and disclosure that led to that Local Rule militate in favor of requiring SaveOnSP to disclose the similar information regarding payment for attorneys' fees or other indemnification information sought through this interrogatory.

Third, SaveOnSP has itself put this information at issue. In its answer, SaveOnSP claimed that "JJHCS has failed to join all necessary parties for a just adjudication of this action." Answer, ECF No. 85, at Affirmative Defenses ¶¶ 52-53. But SaveOnSP did not identify the parties SaveOnSP claims to be "necessary." SaveOnSP's response to this interrogatory will help JJHCS evaluate SaveOnSP's affirmative defense, *see* Fed. R. Civ. P. 26(b)(1), and shed light on the true parties in interest here.

The Court should direct SaveOnSP to provide a complete and accurate response to Interrogatory No. 14 through to the present date.

SaveOnSP's Position

Undeterred by this Court's prior ruling that JJHCS is not entitled to irrelevant information concerning SaveOnSP's finances, ECF No. 89 at 23:12-24, JJHCS again asks to peer into those finances to determine how SaveOnSP might satisfy a judgment. Its request is meritless. SaveOnSP has provided the information required by law: In its initial disclosures, it stated that no insurance policy applied to this claim; if it were receiving litigation funding, it would have filed a statement saying so under Local Rule 7.1.1. *See* Notice to the Bar (July 29, 2021) available at https://www.njd.uscourts.gov/sites/njd/files/NoticetoBarreL.Civ_.R.7.1.1clarification.pdf (no statement required under Local Rule 7.1.1 if a party is not receiving litigation funding). JJHCS concedes that SaveOnSP is not required to make any further disclosures. JJHCS's professed concern about witness credibility does not justify its broad request about every entity who might have responsibility for SaveOnSP's damages or legal fees—JJHCS is free to probe the credibility of individual witnesses in depositions or a trial. And JJHCS's makeweight argument that SaveOnSP somehow put this information at issue by pleading an affirmative defensive that JJHCS has failed to join all necessary parties is simply wrong as a matter of law. *See Stone v. Pepmeyer*, No. 07-CV-1198, 2011 WL 1627076, at *2 (C.D. Ill. Apr. 28, 2011) ("An entity's potential duty to indemnify does not make it a necessary party."). JJHCS's motion should be denied.

* * *

The parties appreciate the Court's attention to this matter and look forward to discussing these issues at the April 13 conference.

Respectfully submitted,

/s/ Katherine M. Lieb
Jeffrey J. Greenbaum
Katherine M. Lieb
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, New Jersey 07102
(973) 643-7000

Adeel A. Mangi
Harry Sandick (admitted *pro hac vice*)
George LoBiondo
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000

Attorneys for Plaintiff Johnson & Johnson Health Care Systems Inc.

/s/ E. Evans Wohlforth, Jr.
E. Evans Wohlforth, Jr.
Robinson & Cole LLP
666 Third Avenue, 20th floor
New York, NY 10017-4132
Main (212) 451-2900
Fax (212) 451-2999
ewohlforth@rc.com

David Elsberg (admitted *pro hac vice*)
Andrew R. Dunlap (admitted *pro hac vice*)
Meredith Nelson (admitted *pro hac vice*)
SELENDY GAY ELSBERG PLLC
1290 Avenue of the Americas
New York, NY 10104

(212) 390-9000
deslberg@selendygay.com
adunlap@selendygay.com
mnelson@selendygay.com

Attorneys for Defendant Save On SP, LLC

Exhibit 1

E. Evans Wohlforth, Jr.
GIBBONS P.C.
One Gateway Center
Newark, NJ 07102-5310
973-596-4500
ewohlforth@gibbonslaw.com

David Elsberg (*admitted pro hac vice*)
Andrew R. Dunlap (*admitted pro hac vice*)
Meredith Nelson (*admitted pro hac vice*)
Elizabeth Snow (*admitted pro hac vice*)
Dominic Budetti (*admitted pro hac vice*)
SELENDY GAY ELSBERG, PLLC
1290 Avenue of the Americas
New York, NY 10104
212-390-9000
deslberg@selendygay.com
adunlap@selendygay.com
mnelson@selendygay.com
esnow@selendygay.com
dbudetti@selendygay.com

Attorneys for Defendant Save On SP, LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC., Plaintiff, v. SAVE ON SP, LLC, Defendant.	Civ. A. No. 22-2632 (JMV) (CLW) **DEFENDANT'S RESPONSES AND OBJECTIONS TO PLAINTIFF'S SECOND SET OF INTERROGATORIES**

To: Jeffrey J. Greenbaum, Esq.
SILLS CUMMIS & GROSS, P.C.
One Riverfront Plaza
Newark, New Jersey 07102
973-643-7000

Adeel A. Mangi, Esq.
Harry Sandick, Esq.
George LoBiondo, Esq.
PATTERSON BELKNAP WEBB
& TYLER LLP
1133 Avenue of the Americas
New York, New York

Attorneys for Plaintiff Johnson & Johnson Health Care Systems Inc.

Pursuant to Federal Rules of Civil Procedure 26 and 33, and Local Civil Rule 33.1, Defendant Save On SP, LLC ("SaveOnSP"), by and through its undersigned counsel, responds and objects to Plaintiff Johnson & Johnson Health Care Systems Inc.'s ("JJHCS") Second Set of Interrogatories, dated February 7, 2023 (the "Interrogatories"). These responses should be deemed to supplement and amend SaveOnSP's disclosures under Rule 26(a) of the Federal Rules of Civil Procedure. If SaveOnSP learns that in some material respect its responses are incomplete or incorrect, SaveOnSP will supplement or correct them if the additional or corrective information has not otherwise been made known to JJHCS during the discovery process or in writing. Fed. R. Civ. P. 26(e)(1)(A). SaveOnSP's responses to these Interrogatories are based on information available to it at the time it made them. SaveOnSP reserves the right to modify or supplement its responses.

GENERAL OBJECTIONS

1. JJHCS does not limit any of its Interrogatories to nonprivileged material. SaveOnSP objects to each Interrogatory to the extent that it seeks disclosure of information which is subject to the attorney-client privilege, the work product doctrine, the common-interest privilege, or any other applicable privileges, immunities, or doctrines.

2. JJHCS does not limit any of its Interrogatories to information within SaveOnSP's possession, custody, or control. SaveOnSP objects to each Interrogatory to the extent that it seeks

disclosure of information that is not within SaveOnSP's possession, custody, or control that SaveOnSP can locate after a reasonable inquiry.

3. JJHCS's Instruction 27 does not define the Time Period with specificity. SaveOnSP objects to each Interrogatory to the extent that it seeks disclosure of information "through the present." SaveOnSP limits its responses herein to information from January 1, 2017 through July 1, 2022.

OBJECTIONS TO DEFINITIONS

4. SaveOnSP objects to the definition of "SaveOnSP" as including attorneys and accountants who may be outside of SaveOnSP's possession, custody, and control. SaveOnSP interprets the term "SaveOnSP" to mean Save On SP, LLC, and any and all predecessors and successors in interest, assignees, parents, subsidiaries, affiliates, divisions or departments, agents, representatives, directors, officers, employees, committees, and all persons or entities acting or purporting to act on behalf or under the control of Save On SP, LLC.

5. SaveOnSP objects to the definition of "SaveOnSP Program," as described in Complaint ¶¶ 9-17, because it mischaracterizes SaveOnSP's services. SaveOnSP will not use this definition.

6. SaveOnSP objects to the definition of "You" and "Your" to the same extent that it objects to the definition of "SaveOnSP."

OBJECTIONS TO INSTRUCTIONS

7. SaveOnSP objects to Instruction No. 24 in Plaintiff's Second Set of Interrogatories to the extent that JJHCS attempts to impose requirements on SaveOnSP beyond those required by the Federal Rules of Civil Procedure, agreed to by the parties, or ordered by the Court.

8. SaveOnSP objects to Instruction No. 25 to the extent it purports to require SaveOnSP to answer Plaintiff's Interrogatories based on knowledge obtained from all available sources. SaveOnSP will answer Plaintiff's Interrogatories based on information in its possession, custody, and control available to it following a reasonable inquiry.

9. SaveOnSP objects to Instruction No. 26 to the extent that JJHCS attempts to impose requirements on SaveOnSP beyond those required by the Federal Rules of Civil Procedure, agreed to by the parties, or ordered by the Court.

10. SaveOnSP uses the term "Janssen Drugs" as defined in SaveOnSP's First Request for Production of Documents to JJHCS, dated November 11, 2022.

Dated: March 9, 2023

By: /s/ E. Evans Wohlforth, Jr.

E. Evans Wohlforth, Jr.
GIBBONS P.C.
One Gateway Center
Newark, NJ 07102-5310
973-596-4500
ewohlforth@gibbonslaw.com

David Elsberg
Andrew R. Dunlap
Meredith Nelson
Elizabeth Snow
Dominic Budetti
SELENDY GAY ELSBERG, PLLC
1290 Avenue of the Americas
New York, NY 10104
212-390-9000
deslberg@selendygay.com
adunlap@selendygay.com
mnelson@selendygay.com
esnow@selendygay.com
dbudetti@selendygay.com

Attorneys for Defendant Save On SP, LLC

RESPONSES TO PLAINTIFF'S SECOND SET OF INTERROGATORIES

INTERROGATORY NO. 13:

Describe what advice or other information SaveOnSP has provided to Payors regarding whether Payors can continue to include Janssen Drugs in the SaveOnSP Program after any changes to the CarePath terms and conditions, including with regard to the December 2021 changes to the CarePath terms and conditions.[1]

RESPONSE:

SaveOnSP objects to this Interrogatory because there is no "SaveOnSP Program" as defined in the Interrogatories. SaveOnSP interprets this term to mean the services that it provides to health plans.

SaveOnSP responds as follows: SaveOnSP has advised its clients when JJHCS changes the terms and conditions for the Janssen Drugs at issue. SaveOnSP has advised its clients that SaveOnSP does not decide whether or not a plan member is eligible for copay assistance under those terms and conditions. On limited occasions, SaveOnSP has provided additional information to Payors regarding changes to the CarePath terms and conditions. Otherwise, SaveOnSP refers JJHCS to documents that it will produce reflecting communications between SaveOnSP and its clients. Fed. R. Civ. P. 33(d).

SaveOnSP designates its response to this Interrogatory as Confidential under the Discovery Confidentiality Order, so-ordered November 22, 2022, ECF. No. 62.

INTERROGATORY NO. 14:

Identify any Entity or individual who has entered into any agreement, or otherwise has any obligation, to advance legal fees incurred by SaveOnSP in this action or to indemnify SaveOnSP in this action for its legal fees, for any damages, or otherwise.

---

[1] *See* Compl. ¶¶ 102-04 (describing December 2021 change to CarePath terms and conditions for Stelara and Tremfya).

RESPONSE:

SaveOnSP objects to this Interrogatory because it seeks information irrelevant to the causes and defenses in this action.

SaveOnSP will not respond to this Interrogatory.

INTERROGATORY NO. 15:

Describe whether and under what circumstances You have advised any Payors to eliminate or alter coverage for certain pharmaceuticals and to arrange for Plan Members to obtain those pharmaceuticals from any source other than Accredo, including (without limitation) independent nonprofit organizations, such as the Johnson & Johnson Patient Assistance Foundation, Inc.

RESPONSE:

SaveOnSP objects to the term "certain pharmaceuticals" as vague and ambiguous.

SaveOnSP objects to this interrogatory because it seeks information irrelevant to the causes and defenses in this action.

SaveOnSP will not respond to this Interrogatory.

CERTIFICATION OF SAVE ON SP, LLC

I, Jody Miller, am the President of Save On SP, LLC ("SaveOnSP"). I am authorized to submit this certification on behalf of SaveOnSP. I certify that the foregoing answers made by me to these Interrogatories are true. I am aware that if any of the foregoing answers are willfully false, SaveOnSP and I are subject to punishment. I certify that in responding to the foregoing Interrogatories, I have furnished all information available to SaveOnSP, its agents, employees and attorneys. As to those answers which are not within my personal knowledge, I certify that I have provided the name and address of every person from whom such information was received or, where the source of such information is documentary, a full description of the document including its location.

Save On SP, LLC

By: _____
Jody Miller
President

Date: March 9, 2023

Exhibit 2

[redacted]

[redacted]

Exhibit 3

Specialty Carve-Outs: What Are the Implications for Patients and Practices?

FROM THE EDITOR

Dawn Holcombe, MBA, FACMPE, ACHE
Editor-in-Chief
President, DGH Consulting, South Windsor, CT

Self-insured employers, perhaps even yours, are being presented with programs called "specialty carve-outs" as an opportunity for saving significant money on the drug portion of their employee benefits. Unfortunately, they are being told that there are "specialty funding" and "lower cost drug options" without being told the full story. As a result, these programs are exposing companies, employees, and patients to significant risks.

Tempting Programs for Self-Insured Employers

The sales pitch from specialty carve-out brokers is very tempting. Specialty drugs comprise almost 50% of a health plan's total drug spend, and the pipeline is growing. The National Alliance for Healthcare Purchaser Coalitions (NAHPC) reports that while 1.2% of all health plan members are high-cost claimants, they make up one-third of total healthcare spending. Michael Thompson, NAHPC's President and Chief Executive Officer, notes that "high-cost claims are the biggest threat to employer-sponsored healthcare coverage today. Only through collective employer action can these risks be mitigated."[1]

How Does a Specialty Carve-Out Program Work?

Each year, self-insured employers work with their third-party administrators, brokers, and other agents to review previous and projected healthcare expenditures, and then they look for opportunities to mitigate their projected expenditures. The specialty carve-out solutions (also known as alternative funding programs) presented to these concerned employers simply eliminate coverage for specific, or in some cases all, specialty drugs. The third-party vendors promote the availability of specialty drug funding and lower cost options to the employer. Then, when an employee discovers that that they are not insured for the treatment they need, they are referred to the contracted specialty carve-out program, which seeks alternative methods to obtain the necessary drugs at little to no cost to the employer (and usually waives any costs to the employee). These alternative methods include searching for funding and medications from patient assistance programs (PAPs) and foundations, as well as sourcing prescriptions from countries other than the United States.

The employer is persuaded to exclude some or all specialty drugs from the employee benefit plan formulary and allow those claims to be administered by a third-party vendor that is often separate from the commercial plan's medical or pharmacy benefit manager. These vendors collect income and other demographics from the now "uninsured" employee and present the situation to PAPs. If they are successful, the drugs are provided through the manufacturer's charitable program or funded through a charitable foundation, at no cost to the employer or employee. The third-party vendor then collects a fee ranging from 20% to 30% of the drug's full list price, or a fixed per-employee, per-month amount for "saving" the employer on its specialty drug obligations.

How These Programs Affect Employees and Providers

Employees are told that signing up with these "preferred" vendors may be mandatory. Marketing materials and benefit letters tout the possibility of obtaining expensive drugs at a sharply reduced cost or no cost at all. However, if employees do not use the program to obtain these drugs, they will be held liable for up to the full amount of the drug manufacturer's PAP limits, meaning they could be expected to pay as much as $20,000 or $30,000 per month. These penalty payments would not be applied to their insurance deductibles or co-insurance requirements.

If employees *do* enroll and use a third-party vendor, they will be expected to receive the drugs either through direct shipment (both brown-bagging [home] and white-bagging [physician's office]) or from whichever source the vendor chooses, such as an unknown distributor or even an imported drug from outside of the country. Delivery times may range from a few days to 5 to 7 weeks, depending on the source. To make matters worse, refrigerated product delivery is complicated and not easily controlled.

When patients are told that they must participate in these types of third-party programs, the provider is also affected. The drug may be brown-bag shipped to the patient or white-bag shipped to the provider. If the provider chooses not to use a drug shipped from an unknown source or country, the patient is forced to choose to either decline participation in the program (with the financial penalties discussed earlier) or find an alternate provider who will accept the conditions of the program. In the fine print of the client documents for some of these vendors, there is added language specifying that patients must contact their physician if they have any unexpected side effects from medications ordered through that vendor, which would be a source not known to (or trusted by) the physician, and possibly imported wholesale against current US law.

Several providers have already reported to me their serious concerns regarding the health and safety of their patients because of these programs. These include the following:

- Patients are being told that they are not actually insured
- Patients and providers must wait for the vendor to go through their internal enrollment and implementation process
- Patients are experiencing significant stress after being told they may not receive the treatment that their physician recommends, from a source that their physician trusts
- Patients and providers are facing the financial consequences of not using the third-party vendors
- Providers are experiencing uncertainty regarding patients' benefits coverage when it was assumed that they were fully insured under their employer's benefit plan.

Egregious Aspects of Specialty Carve-Out Programs

Essential Health Benefits Are Being Denied

The Patient Protection and Affordable Care Act (ACA) requires individual and small group markets to cover 10 essential health benefits, including ambulatory patient services, prescription drugs, and preventative and wellness services and chronic disease management.[2]

Specialty carve-out vendors improperly designate one or more specialty prescription drugs as a "nonessential" health benefit and therefore not subject to the ACA's essential health benefit limits on the consumer's annual out-of-pocket costs. The vendors then declare that they are able to charge patients penalties for nonparticipation in their programs equal to the full amount of patient assistance available through the drug manufacturer's PAP and refuse to count those penalty copays towards the consumer's annual deductible and out-of-pocket costs.

Illegal Wholesale Importation of Drugs into the United States

The US Food & Drug Administration (FDA) guidance on importation of drugs into the United States asserts that in most circumstances, it is illegal for individuals to import drugs into the country for personal use.[3] "The Federal Food, Drug and Cosmetic Act prohibits the interstate shipment of "unapproved drugs," which includes the importation of unapproved drugs from outside of the United States. Unapproved drugs include those not manufactured according to FDA standards."[4-6]

If a drug has not been FDA-approved for use in the United States, even if it has been approved in another country, it is illegal to import because the FDA cannot ensure its safety and efficacy.[3] However, the FDA does not typically object to the personal importation of drugs—even those that it has not approved—in the following specific scenarios.[3]

- The drug is being used for a serious condition for which effective treatment is not available in the United States
- There is no commercialization or promotion of the drug to US residents
- The drug is considered to not represent an unreasonable risk
- The individual importing the drug verifies in writing that it is for his or her own use, and provides contact information for the physician providing treatment or shows the product is for the continuation of treatment initiated in another country
- Generally, not more than a 3-month supply of the drug is imported.

However, specialty carve-out vendors are engaging in wholesale importation of massive quantities of prescription drugs—without reference to pedigree or sourcing—from countries such as Canada, India, and Australia. One justification that I have personally heard from a vendor is that, yes, it is technically illegal, but "a blind eye is turned on the practice because drugs in the United States are too costly, and the importation is justified because of the savings on drug costs to employers and employees."

Employers and employees are made aware of potential cost-savings, but not the significant medical risks associated with turning to illegally imported drugs. Physicians cannot accept the risk of administering prescription drugs to vulnerable patients without knowing and trusting that those drugs have been legally and ethically sourced with a responsible pedigree.

Draining Already Limited Support for Needy Patients

When specialty carve-out programs deliberately block employed patients from coverage for a specific drug or illness, they are also targeting other vulnerable patients. PAPs and foundation programs set aside limited funds for needy patients. By draining PAPs and foundation support for their customers, these vendors are putting the PAP and foundation programs themselves at risk for no longer being able to help those for whom they were established to serve.

"Bait and Switch" Insurance Health Coverage

When a self-insured employer allows a third-party vendor to determine that specific prescription drugs are not covered, there is usually no advance notification given to the employee, who will be directly affected. Employees usually discover that the drugs they need will not be covered when they receive a "no coverage" notice upon their diagnosis and planned treatment. Then, they are told to enroll in the third-party vendor program and provide detailed financial and personal information so that the vendor can pursue alternative funding. Promises are made that the treatment may become available at minimal or no cost to the employee. However, if the third-party vendor is unsuccessful in obtaining alternative funding or the necessary drug, the employee is frequently suddenly returned to the regular insurance health benefit and given the coverage that they thought they had all along before being deemed "uncovered." This "bait and switch" is very concerning to employers, employees, state insurance regulators, and consumer advocacy groups.

Who Are the Third-Party Vendors?

Unfortunately, this is a growing business niche with a compelling story of cost-savings if one does not look too deeply into the details (which many employers and employees have not done). It may be difficult to detect the presence of third-party vendors because most providers are not accustomed to employed and insured patients receiving wholesale denials from their employers. Furthermore, foundations and PAPs are not accustomed to questioning whether a statement of a patient being uninsured for a drug is driven by actually having no insurance at all, or if it is an employed patient who may now be uninsured for a targeted drug. If you are a self-insured employer, your broker may already have made one of these programs part of your own insurance plan.

Some of these companies include ImpaxRx, PaydHealth, PayerMatrix, RxFree4me, SHARx, SavOnSP, ScriptSourcing, and at least a dozen more. Their public websites tout the potential savings but are fairly sparse on the details of how the process works or where the savings and drugs come from. I was able to dig deep into the Internet and find YouTube marketing segments, as well as actual contracts with clients, which reveal the flaws in these programs.

What Are the Next Steps?

We need to protect our patients. These programs offer a compelling message about savings but fail to present the dark side, namely, the potential for patient harm, confusion, and coercion; unnecessary treatment delays; the legal and ethical challenges of drug importation; bait and switch insurance coverage games; and the danger of draining funds from PAPs and foundations. I have already heard from foundations and manufacturers that are seeing dramatic increases in the demands for their limited patient support. At least one manufacturer has recently posted changes to its PAPs that limit coverage to unemployed patients.

We can take the following steps to protect our patients:

- Become aware of the existence of these programs and track their impact in our own practices
- Document diseases, drugs, employers, unions, and clients affected by these vendors
- Document adverse consequences for patients as they are forced through the process, rates of substitution, medication sources, frequency of recoverage for patients
- Track white-bagging and brown-bagging program demands and related communications to physicians and patients under these programs
- Align with state oncology societies, the National Oncology State Network, and other organizations to address these talking points and issues.

If you see something, say something. I welcome your comments and can be reached at **dawnho@aol.com**. I am actively working with several organizations and partners to challenge these programs, and would appreciate observations from affected practices, foundations, manufacturers, and patients.

Sources for drug funding are limited and exist for patients who are truly in need. The business model of these specialty carve-out vendors is to bill employers for "savings generated" by selectively uninsuring treatments for specific diseases, orphan diseases and cancer for otherwise-insured employed patients, and grabbing monies set aside for charitable purposes or importing lower cost drugs illegally from outside the United States in the name of saving employers money on their drug spend. This violates the intent of Essential Health Benefit designation, drains limited funds away from more needy ill patients, and targets people at their most vulnerable. It is my hope that useful feedback and guidance may help to mitigate the impact of these vendors and help employers understand the risks and adverse consequences of these programs.

References

1. National Alliance for Healthcare Purchaser Coalitions. Rethinking how we mitigate high-cost claims. June 11, 2021. https://connect.nationalalliancehealth.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=2b646e95-a9a9-1bb7-6c2c-572117f86850&forceDialog=0. Accessed November 22, 2022.
2. Centers for Medicare & Medicaid Services. Information on essential health benefits (EHB) benchmark plans. www.cms.gov/cciio/resources/data-resources/ehb. Accessed November 22, 2022.
3. US Food & Drug Administration. Is it legal for me to personally import drugs? January 26, 2021. www.fda.gov/about-fda/fda-basics/it-legal-me-personally-import-drugs#:~:text=In%20most%20circumstances%2C%20it%20is,sale%20in%20the%20United%20States. Accessed November 22, 2022.
4. Federal Food, Drug, and Cosmetic Act, 21 USC §331 (2010).
5. Federal Food, Drug, and Cosmetic Act, 21 USC §335(a) (2010).
6. Pestaina K, Stamm C. Prescription drug importation gets renewed attention. February 21, 2020. www.mercer.com/content/dam/mercer/attachments/global/law-and-policy/gl-2020-prescription-drug-importation-gets-renewed-attention.pdf?. Accessed November 22, 2022.

Related Articles

Specialty Carve-Out Models Cost Patients and Employers More Than They Disclose
By Dawn Holcombe, MBA, FACMPE, ACHE

February 2023, Vol 13, No 2

FROM THE EDITOR

Still a Rocky Road Ahead for Biosimilars?

By Dawn Holcombe, MBA, FACMPE, ACHE

October 2022, Vol 12, No 10

FROM THE EDITOR

Getting Real with the New Enhancing Oncology Model

By Dawn Holcombe, MBA, FACMPE, ACHE

August 2022, Vol 12, No 8

FROM THE EDITOR

Digital Therapeutics Is the Key to New Patient Management Demands for Physicians

By Cindy Borassi; Bob Gold, MS; Dawn Holcombe, MBA, FACMPE, ACHE

August 2022, Vol 12, No 8

HEALTHCARE TECHNOLOGY

Exhibit 4

TUESDAY, AUGUST 02, 2022

The Shady Business of Specialty Carve-Outs, a.k.a., Alternative Funding Programs

How an insured beneficiary applies for charitable patient assistance

Watch out! Plan sponsors are getting even bolder in their attempts to grab financial support intended for patients. The latest scam is called a **specialty carve-out**.

Here's the game: A commercial plan eliminates coverage for all specialty drugs. Beneficiaries are then shunted over to a charitable foundation, because they are now disguised as uninsured—at least for specialty drugs. Naturally, the vendor skims a healthy share of the charity's money.

In addition to the ethical and compliance issues, some vendors raise safety risks by sourcing prescriptions from non-U.S. pharmacies as a backup.

The Orwellian euphemism for this "benefit" design: alternative funding program.

A new survey reveals that an astounding four out of 10 commercial plans are already using, or exploring the use of, these specialty carve-out programs. Yikes.

Read on for an overview of these shady programs—and the many problems they are creating.

PAP 101

Patient assistance programs (PAP) focus on patients who meet financial eligibility criteria —those without insurance and those denied coverage by their commercial plans. PAPs therefore differ from **copayment offset programs** that cover a commercially insured beneficiary's out-of-pocket costs. Copayment offset programs may not be used by beneficiaries of any federal healthcare program, including Medicare Part D. PAPs can, however, support patients with government-sponsored insurance.

PAPs are often incorporated as 501(c)(3) nonprofit charitable foundations. Exhibit 122 of our *2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* lists 10 of the largest PAPs funded by pharmaceutical manufacturers. These organizations have been subject to controversy about their operations.

For more on the economics of manufacturer's out-of-pocket support, see our 2022 pharmacy/PBM report.

MASTERS OF DISGUISE

PAPs enable **specialty carve-outs**, also known as alternative funding programs (AFP). Here's how the scheme works:

- Some or all specialty drugs are administered by a secretive third-party vendor that is separate from the commercial plan's PBM. Examples of these players include ImpaxRx, PaydHealth, PayerMatrix, RxFree4me, SHARx (an aptonym?), and Script Sourcing. (I won't promote these companies by linking to their uninformative web sites.)
- These specialty drugs are **excluded** from the plan's formulary, so that a patient technically has no coverage for the specialty drug.
- The third-party vendor helps the patient disguise themselves as "uninsured" so they can apply for the manufacturer's PAP funds to cover the cost of the prescriptions. (When contacting the manufacturer, I have heard that some vendors will even impersonate the patient.) These prescriptions are typically filled by noncommercial pharmacies that are operated by specialty hub service companies funded by the manufacturer.
- The manufacturer ends up paying the full cost of the prescription and the pharmacy services. Meanwhile, the plan sponsor incurs no costs for the specialty drug.
- I estimate that the third-party vendors retain up to 20% to 25% of a drug's full list price, i.e., the value of charitable funds provided to the patient. Some may get paid a generous per-employee, per-month fee.

If a manufacturer's PAP detects the fraud, then some carve-out vendors will seek to source products from pharmacies located outside the United States. This is not permitted, as the FDA's BeSafeRx program points out.

Drug Channels is written by Adam J. Fein, Ph.D. Dr. Fein is CEO of Drug Channels Institute. Read More...

Email Dr. Fein
Follow on LinkedIn
@DrugChannels

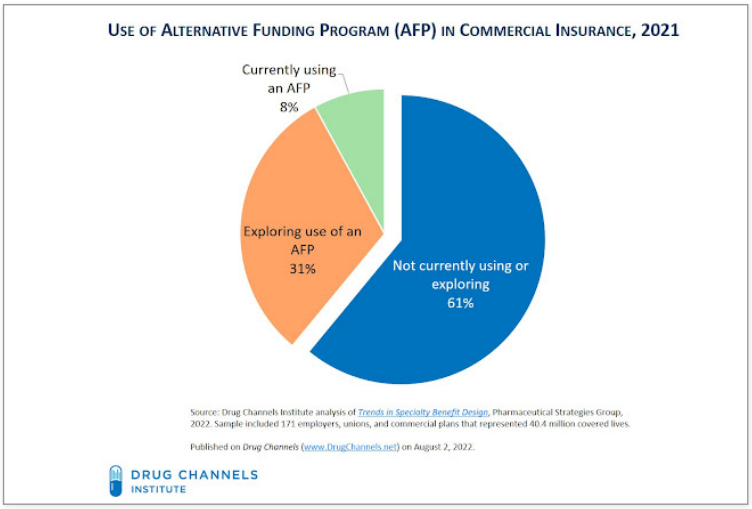
You will surely not be surprised to learn that these vendors' webpages never really explain how drug savings are generated—or how the vendors earn their profits.

MONEY FOR ME, NOT THEE

To evaluate the prevalence of specialty carve-out programs, we again rely on ***Trends in Specialty Benefit Design***, the excellent recent report from Pharmaceutical Strategies Group (PSG). (The report is free with registration.) This survey, which was conducted in mid-2021, included 171 employers, unions, and commercial plans that represented 40.4 million covered lives.

The survey asked directly about alternative funding programs. As you can see below, 8% of plans are already using AFPs, while a further 31% are exploring their use.

[Click to Enlarge]



As far as I know, this survey represents the only public data on the current use of AFPs. While there is no historical data, I believe that the use and interest in these programs has grown dramatically in the past few years. I've been told that some benefit consultants are including specialty carve-out programs in their RFP responses for the 2023 and 2024 plan years.

WHAT'S WRONG?

Some payers will probably see no problem here. They justify sticking it to "big pharma" by getting free drugs for their beneficiaries.

However, these programs can have significant downsides for both plans and patients:

- Commercial payers are accessing need-based funds from charitable foundations that were established to help underinsured and uninsured patients. Truly needy patients must compete for PAP funds with financially sound payers and patients who would not otherwise be eligible for charitable support.
- Patients often face treatment delays due to the application process for PAP funds. They may also be encouraged to use the product with a more favorable PAP program rather than the most clinically appropriate product.
- Plan sponsors incur higher administration costs, because the carve-out vendor must coordinate with the primary PBM that is administering the pharmacy benefit. The plan sponsor also faces higher plan costs due to higher fees or lower rebates and discounts from their PBM.

  ICYMI, I explained why pharmacy benefit managers (PBMs) prefer copay maximizers to specialty carve-out programs in Four Reasons Why PBMs Gain As Maximizers Overtake Copay Accumulators.
- Third-party vendors can earn a big chunk (20% to 25%) of the total PAP funds provided by the manufacturer. Like the secretive vendors behind copay maximizer programs, the carve-out vendors rake in egregious fees that are highly disproportionate to the costs of their activities. These fees come from the plan.
- Self-insured plans face numerous ERISA and IRS-related compliance issues. Click here for a helpful overview of these issues from Vivio Health. This document also warns: "Manufacturers and agencies providing alternative funding may claim misrepresentation because alternative funding depends on recipients having no insurance." Plans are also taking enormous safety risks by enabling carve-out vendors to source prescriptions from unlicensed and unsafe overseas pharmacies.

As I noted during last week's **Specialty Drugs Update: Trends, Controversies, and Outlook** webinar, carve-outs are the latest example of how plans and PBMs want to use

manufacturers' copay support and patient assistance programs as a source of funding and profits.

As with many seedy corners of the drug channel: It's good money, if you can get away with it. Unfortunately, patients and plan are the losers from programs that misrepresent the patient's true financial situation while undermining the intent and operations of charitable patient assistance programs.

CORRECTION: The text has been updated to reflect that fact that the AFP vendor's fees are paid by the plan sponsor, not the charitable foundation.

Posted by Adam J. Fein, Ph.D. on Tuesday, August 02, 2022 10 Comments
Labels: Benefit Design, Co-pay Offset Programs, Costs/Reimbursement, Specialty Drugs

▼ 2022 (126)
- ► December 2022 (11)
- ► November 2022 (8)
- ► October 2022 (10)
- ► September 2022 (10)
- ▼ August 2022 (9)
  - Your Brand Just Got Added to a Must-Have Formulary...
  - Drug Channels News Roundup, August 2022: Gov. Dean...
  - Informa Connect's Copay, Reimbursement and Access ...
  - The Next Great Healthcare Surge: A 'Diagnosis Expl...
  - The 340B Program Climbed to $44 Billion in 2021—Wi...
  - Improving Out-of-Pocket Cost Transparency For Phys...
  - Texas Shows Us Where PBMs' Rebates Go
  - Three Technology Tactics for Overcoming Prior Auth...
  - The Shady Business of Specialty Carve-Outs, a.k.a....
- ► July 2022 (14)
- ► June 2022 (10)
- ► May 2022 (8)
- ► April 2022 (15)
- ► March 2022 (12)
- ► February 2022 (10)
- ► January 2022 (9)

► 2021 (128)
► 2020 (132)
► 2019 (148)
► 2018 (158)
► 2017 (155)
► 2016 (155)
► 2015 (157)
► 2014 (148)
► 2013 (147)
► 2012 (145)
► 2011 (137)
► 2010 (139)
► 2009 (108)
► 2008 (94)
► 2007 (115)
► 2006 (57)

DRUG CHANNELS IN THE NEWS

Drug Middlemen Accused of Price Fixing by Ohio Attorney General *The Wall Street Journal*

Drugmakers push back on a clever tactic employers use to avoid paying for specialty medicines *STAT*

New Drug Channels Institute Study Analyzes Impact of Inflation Reduction Act on U.S. Prescription Market *PR Web*

The End of AbbVie's $200 Billion Monopoly Won't Sink the Stock *The Wall Street Journal*

Amgen pricing for its Humira biosimilar may benefit PBMs and insurers more than patients *STAT*

U.S. Appeals Court Sides With Drugmakers on Discount Program *The Wall Street Journal*

Industry Will Continue to See 340B, Patient-Paid Prescription Impact as IRA Looms *AIS*

What do you think?

28 Responses

18	0	0	7	3
Upvote	Funny	Love	Angry	Sad

Comments and reactions for this thread are now closed.

10 Comments Login ▾

1 Share Best Newest Oldest

Brenda Motheral
8 months ago

Glad you are bringing attention to the Alternative Funding Programs and the challenges associated with them. We have seen the terms “Alternative Funding” and “Specialty Carve-Out” used interchangeably, which can create confusion for plan sponsors. Alternative Funding is inherently different from a Specialty PBM Carve-Out. As you pointed out, Alternative Funding vendors eliminate coverage of specialty drugs altogether whereas a Specialty Carve-Out can is a term that is also used to describe a model in which services are carved out from the traditional PBM and provided by a PBM who specializes in the management of specialty patients (e.g. Archimedes, Vivio). In the latter case, coverage of specialty drugs is maintained and best practices for cost management are applied. For more information on the divergent models, go to https://archimedesrx.com/wh....

0 0 Share ›

Adam J. Fein Mod → Brenda Motheral
8 months ago

Thanks for your comment, Brenda.

I agree with your distinction. But in practice, many of the AFP vendors use such terms as "specialty carve-out" and "specialty cost containment." This has created a lot of marketplace confusion.

As the AFP fraud scales, the true specialty PBM carve-out vendors (such as your company) will surely be working hard to clarify the differences.

0 0 Share ›

Adam J. Fein Mod → Adam J. Fein
8 months ago edited

For instance, even WTW lumped Archimedes into the

Health

Expect Industry Impact From Vertical Integration, Provider M&A Activity, Humira Biosimilars *AIS Health*

January’s new drug price increases take off without overcompensating for upcoming inflation-linked rebates *Endpoints*

Pharmacies Hit By Restrictions On 340B Drug Discounts *Inside Health Policy*

A Softbank-backed pharmacy startup is working to tackle a $300-billion-a-year prescription drug crisis *Fortune*

Tackling cancer while battling the insurance system *The Washington Post*

Industry Experts Question Alternative Funding Companies That Carve Out Some Specialty Drugs, ‘Abuse’ Charities *AIS Health*

340B Contract Pharmacy Restrictions Slowed Program’s 2021 Spending Trajectory, But Not Much *Pink Sheet*

Sales from controversial drug discount program rose to $44 billion last year, *STAT*

Industry Expert: Specialty Pharmacy Market Is at ‘Inflection Point’, *AIS Health*

Meet the Newest Members of our Advisory Board, *Alto Pharmacy*

Rounding Up The Usual Suspects Won’t Alleviate Inflation *Forbes*

Gottlieb, Fein Discuss COVID-19, Accelerated Approvals, and Drug Pricing at Asembia 2022 *AJMC*

Pharma Companies Making 340B Restrictions Continue To Pile Up *HealthLeaders Media*

Big 3 Implement Conflicting Formulary Exclusions on Biosimilars *RADAR on Drug Benefits*

Rite Aid and CVS to close stores in 2022. What is driving the downturn? *WHYY*

'It is legal extortion': Diabetics pay steep price for insulin as rebates drive up costs *USA Today*

INDUSTRY NEWS AND BLOGS

STAT
Next abortion battles may be among states with clashing laws

Drug Store News - Pharmacy
Publix announces 2022 Pharmacy Rxcellence Award recipients

PR Newswire: Health Insurance
Battelle Awarded Federal Contract to Support Healthcare Performance Measurement

Fierce Pharma
In legal battle over abortion pill, conflicting rulings leave future access up in the air

Endpoints
A new cell therapy biotech emerges to find solid tumor-killing immune cells in patients' blood

Chain Drug Review
Walgreens returns as exclusive retail partner of Red Nose Day

PCMA
America’s Pharmacy Benefit Companies Secure Billions of Dollars in Savings for Taxpayers

Newer Post Home Older Post

For instance, even WTW lumped Accredo in the same category as PaydHealth, Payer Matrix, and SHARx. See How employers can manage the cost of specialty pharmacy benefits (March 2021).

0 0 Share ›

Brenda Motheral ↗ Adam J. Fein
8 months ago

Thank you for pointing this out Adam. The nomenclature is certainly a challenge. We are hoping that the description "Alternative Funding Vendors" is ultimately where the market lands in describing those vendors who eliminate coverage as they are apples and oranges to Specialty PBM Carve Outs.

1 0 Share ›

Pramod John ↗ Adam J. Fein
8 months ago

Adam, we are offended that WTW didn't do their homework and put out misinformation placing VIVIO in the same category as the AFP vendors. We aren't an exclusion vendor and don't believe in the model, hence why we put out the document about the associated compliance issues. In our case, 'carve-out' is in reference to our management of specialty instead of the existing PBMs, and we don't use formularies or own any infrastructure, we simply care about cost-effective outcomes for the members we serve.

0 0 Share ›

Stephen Callahan
8 months ago

Hi Adam,

This was a fantastic article! One step in the process I'm curious about is when a specialty drug comes back as not covered, how do they get linked up with the carve-out vendor?

Does the plan communicate to the patient and/or physician on how to reach out to the vendor? Or does the vendor reach out to these parties directly after the plan doesn't authorize the script?

1 0 Share ›

Adam J. Fein Mod ↗ Stephen Callahan
8 months ago

Great question. I'm sure there is some sort of process, but it's not hard to imagine how patients could be harmed along the way.

0 0 Share ›

David Calabrese
8 months ago

Thanks for bringing this issue to the forefront Adam. I must say that it is also both disappointing and frustrating that the pharmaceutical manufacturers have stood by to allow this type of misuse of much-needed foundational dollars in this way. Are there any efforts underway, to your knowledge, at the Pharma level to better protect these funds moving forward so that they benefit those for whom they were originally intended?

0 0 Share ›

Ryan Hotchkiss

Healthcare Economist
FDA-Approved Drugs Not Recommended for Use or Reimbursement in Other Countries

The Catalyst (PhRMA)
ICYMI: PhRMA President and CEO Stephen J. Ubl discusses patient affordability

Biosimilars Review & Report
Biosimilar Bytes

Show All

RH **Ryan Hotchkiss**
8 months ago

Adam, is it legal for commercial payers to do this? Are payers that implement this policy subject to disciplinary action? Finally, can these activities be reported to an agency or organization?

0 0 Share ›

L **Lindsay Butler**
8 months ago

I work as a nurse in a specialty area. I recently had a patient with insurance that excluded all specialty drugs from coverage. I manage all of our Biologics, so when I received this information, I had him apply for patient assistance directly through the manufacturer. I also assist our patients with this process. I noticed that another pharmacy had reached out to the patient trying to "help" with this process as well. I then began receiving prescription requests from this pharmacy. I imagine that his insurance company provided the pharmacy with his contact information and the name of the drug requested. I certainly did not send them any information or request their assistance. There was another company affiliation listed on the Rx request so I visited the site. There was not a lot of information provided but it did say they outsourced drugs from other countries like New Zealand and Canada. I am consistently seeing more and more of this nonsense and maximizer plans. I hope that managing this patient without the assistance of this third party prevented them from stealing patient access funds.

0 0 Share ›